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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,372	12/21/2001	Jeffrey A. Trogolo	A-035 US	5146

7590 05/23/2005

AGION TECHNOLOGIES
60 Audubon Road
Wakefield, MA 01880

EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,372	TROGOLO ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-23,38-45 and 51-62* is/are pending in the application.

4a) Of the above claim(s) *41 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-23,38-40,42,44,45 and 51-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7,10-23,38-45 and 51-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner expands the elections of species to include all hydrophilic polymers with respect to the encapsulating polymer, all inorganic antimicrobials, and all addition matrix polymers which are non-hydrophilic. As such, claims 1-7, 10-23, 38-40, 42, 44,45, 51-62 are directed to the elected invention with claims 41, 43 withdrawn as directed to the nonelected invention.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,10, 11, 13-15, 23, 38, 39,42, 55 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP 11-222402.

JP 11-222402 expressly discloses antimicrobial acrylamide particles (mean particle diameter of about 60-90 nanometers, 90-120 nanometers, 90-120 nanometers) containing silver (22.8% by weight, 35.2% by weight and 25.7% by weight) which is incorporated into Aronix

UV-3701 or ARON NS-1200 and hardened to form a film falling within the scope of applicant's claims (Paragraphs 0043-0055).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-4, 10-17, 19-21,23, 38-40, 42, 44,45,51-55, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 11-222402 in view of JP 4-66512 and Turner et al. (US 2003/0043341).

JP 11-222402 discloses antimicrobial acrylamide particles (mean particle diameter of about 60-90 nanometers, 90-120 nanometers, 90-120 nanometers) containing silver (22.8% by weight, 35.2% by weight and 25.7% by weight) which is incorporated into Aronix UV-3701 or ARON NS-1200 and hardened to form a film (Paragraphs 0043-0055). It is disclosed that the hydrophilic polymer particle containing the antimicrobial metal, such as silver, platinum, copper, zinc, nickel, cobalt, molybdenum, chromium etc., can have a diameter of 0.1 nanometers to 100 micrometers and that the particle can be incorporated into a resin (Paragraphs 0006,0007, 0023-0025). It is disclosed that the hydrophilic polymer can be composed of hydroxyl content monomers, such as alkyl (meth) acrylate, nitrogen content monomers, such as vinyl-pyrrolidone and acrylamide, and poly isocyanate and can contain two or more different hydrophilic units, is compatible with the hydrophobic resin (Paragraphs 0008-0010). It is disclosed that the antibacterial metal can be in the form of a complex with a quaternary ammonium compound which also has antibacterial activity (Paragraph 0027). It is disclosed that the resin can be

selected from poly ethylene, poly propylene, ABS, epoxy resin, styrene resin, poly vinyl chloride (Paragraph 0036).

JP 4-66512 (citation is to the English language translation provided by Applicant) disclose an antimicrobial silver salt which is coated with polyurethane resin prepared from poly isocyanate (pgs. 7,9-12). It is disclosed that the coated antimicrobial silver salt can be incorporated into a thermoplastic or thermosetting resin (Pgs. 13-15).

Turner et al. discloses that sodium nitrate reduces discoloration caused by silver (Paragraphs 0061, 0062).

Claims 1-7, 10-23,38-40,42,44,45,51-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 4-66512 in view of Takebayashi et al. (US Pat. 6,113,936), Niira et al. (US Pat. 5,556,699), Wada et al. (US Pat. 3,981,970) and Turner et al. (US 2003/0043341) for the reasons of record and the further reasons below.

JP 4-66512 (citation is to the English language translation provided by Applicant) disclose a silver zeolite which is coated with polyurethane resin (pgs. 7, 8, 11,12). It is disclosed that the coated silver zeolite can be incorporated into a thermoplastic or thermosetting resin (Pgs. 13-15). An example is disclosed in which the antimicrobial zeolite is prepared by addition of silver nitrate and ammonia and thereafter coated with the polyurethane in an amount of 1.5% by weight or 3% by weight (Pgs. 16-18). An example is disclosed in which said coated zeolite is incorporated into a polypropylene resin which thereby exhibits antimicrobial activity (Pgs. 19-21).

Takebayashi et al. disclose a method of microencapsulating silver zeolite with polyurethane where the average diameter of the obtained microcapsule is usually from 0.1 to 300 micrometers, preferably from 0.5 to 200 micrometers and the core particle is usually from 0.1 to

200 micrometers, preferably 0.5 to 100 micrometers (See entire reference, especially Column 2, lines 1-13, Column 3, line 9, Column 4, line 66, Column 5, lines 60-64).

Niira et al. teach that antibiotic zeolites containing silver which further incorporate ammonium ions effectively prevent discoloration of resins into which the antibiotic zeolites are incorporated (Column 2, lines 11-23).

Wada et al. teach that the exchange of cations in zeolite is a equilibrium reaction (Column 1, lines 1-48). An exchange reaction process is taught whereby silver ions are introduced to sodium containing zeolite with the result being silver zeolite plus any excess silver ion and sodium ion (Column 3, lines 5-11). An exchange reaction process is taught in which nitric acid is introduced into silver zeolite with the result being hydrogen zeolite, silver nitrate and any excess nitric acid (Column 3, lines 12-15).

Turner et al. discloses that sodium nitrate reduces discoloration caused by silver (Paragraphs 0061, 0062).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an inorganic antimicrobial which is encapsulated with hydrophilic polymer having an average diameter of about 2000 microns or less, optionally further comprising an ammonium salt or sodium nitrate or optionally further incorporated into an addition polymer. However, the prior art amply suggests the same are antibacterial silver zeolites which are incorporated into addition polymers, the combination antibacterial silver zeolites and hydrophilic polymers, such as polyurethane, the use of ammonium ions and the exchange of silver with sodium ions and nitric acid are known in the art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of antibacterial silver zeolites and hydrophilic

polymers would result in increased antibacterial activity, that addition of ammonium ions would inhibit discoloration of polymer resins, in which the antibacterial zeolite/hydrophilic polymer is incorporated and that the addition of a salt of sodium ion and nitric acid, i.e. sodium nitrate, would drive the silver ions out of the zeolite thereby increasing the amount of free silver ions available for antibacterial effect.

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-4, 10, 11, 13-15, 22, 23, 51, 52, 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lew et al. (US Pat 5,599,583).

Lew et al. disclose encapsulation of fungicides such as copper salts with water soluble polymers, including PEG strengthened with polyvinylpyrrolidone (Column 3, lines 23-40, 44,45, Column 5, lines 55-60). It is disclosed that the active ingredient solids exhibit a size of less than about 100 micrometers in diameter and that the product capsules should be formed within the range from about 150 micrometers to about 1500 micrometers (column 4, lines 51-63, Column 7, lines 18-25).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a inorganic antimicrobial which is encapsulated with hydrophilic polymer having an average diameter of about 2000 microns or less. However, the prior art amply suggests the same as the prior art discloses the copper salt fungicide encapsulated with water soluble polymers having diameter of from about 150 to 1500 micrometers. As such, it would

have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the encapsulation would render the copper salt easy to handle, reduce or eliminate exposure concerns and provide a measure of control over the rate, timing and duration of the copper salt (Column 1, lines 35-43).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-4, 10, 11, 13-17, 22, 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapler et al. (US Pat 5,382,424).

Stapler et al. disclose encapsulation of antimicrobials, including quaternary ammonium salts and zinc and copper salts in gelatin, polyvinyl alcohol sucrose esters, gums, sucrose esters and sugar candy type materials used in cough drops and mints (Column 2, lines 8-13, 23-28). It is disclosed that the shell thickness is preferably in the range of about 30 micrometers to about 2 mm, preferably from about 70 micrometers to about 110 micrometers and the particle diameter is generally in the range of from about 2 mm to about 9 mm, preferably from about 3 to about 7 mm (Column 2, lines 13-21). It is disclosed that the amount of antimicrobial agents is from about 0.001% to 2% of the total core contents (Column 2, lines 34-36). Examples are disclosed contain gelatin, saccharin, and cetyl pyridinium chloride or zinc chloride (Column 3, 15-45).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a inorganic antimicrobial which is encapsulated with hydrophilic polymer having an average diameter of about 2000 microns or less, optionally further comprising an ammonium compound. However, the prior art amply suggests the same as the prior art discloses the ammonium and zinc and copper salt antimicrobials encapsulated with gelatin, polyvinyl

alcohol, sucrose esters and/or sugar candy materials having a diameter of about 2 mm.. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the encapsulation of a core containing the antimicrobial would allow control of breath odor without having to expectorate as would be required with a mouthwash (Column 1, lines 15-25). Further, it would have been well within the skill of one of ordinary skill in the art to combine the ammonium compound and copper and/or zinc salt with the expectation that the combination would also have antimicrobial activity.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 10-23, 38-40, 42, 44,45, 51-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 10-

22, 33, 34,45, 47-62 of copending Application No. 10/032,370 in view of Hagiwara et al. (US Pat. 4,775,585) and Konagaya et al. (US Pat. 6,013,275).

Copending Application No. 10/032,370 claims a microcapsule comprising an antimicrobial agent, such as silver zeolite, dispersed in a hydrophilic polymer having a water absorption at equilibrium of at least about 5% by weight, such as polyhydroxyethyl methacrylate and polyurethane , with the longest dimension being less than about 3000 micron, such as about 5-1000 microns, and an aspect ratio greater than about 2, such as about 4 to about 100 (Claims 1,7,33,47). The Application claims the addition of a discoloration inhibiting agent, such as ammonium compound and a dopant agent such as sodium nitrate (Claims 17, 21). The Application claims incorporation of the microcapsule into a non-hydrophilic polymer (Claim 45).

Hagiwara et al. teach the incorporation of antibacterial silver zeolite particles in polymers such as ABS resins (See entire reference, especially, Column 4, lines 44-58).

Konagaya et al. teach that the antibacterial activity of silver zeolite can be increased by incorporating the same in a hydrophilic substance which is an organic compound or a high molecular compound containing at least one of a hydroxyl group, amino group, amide group, carboxyl group or alkali metal salts thereof, such as homopolymers or copolymers of polyacrylic acid, homopolymers of copolymers of polymethacrylic acid or 2-hydroxyethyl methacrylate and that the same can be incorporated into a suitable thermoplastic or thermosetting resin (Column 3, lines 16-26, Column 5, lines 2-13, Column 8, lines 48-51, Column 9, lines 4-6, Column 10, lines 34-36, Column 13, lines 1-14).

The difference between the claims of the copending Application and the claimed invention is that the copending Application does not expressly disclose a specific polymer, such ABS, into which the microcapsule is incorporated. However, the prior art amply suggests the

same as the prior art discloses the incorporation of silver zeolite in to resins, such as ABS resins. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that ABS resins would be a suitable for incorporation of the claimed microcapsule.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of said copending Application to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the claims and prior art references.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
May 19, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600